EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Health in all Policies, Global Health, Tobacco Control

Expert Subgroup Group on the Technical Implementation on the Common Reporting and Notification Formats under Articles 5 and 20 of Directive 2014/40/EU

Final Summary record

Webinar date: 31 March 2016, 10.00 – 12:00

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair reminded participants about the deadline for SLA signature, and pointed out that storage of data provided by the Commission can only be guaranteed for those Member States who have completed the signature process on time. The Chair asked Member States to communicate as soon as possible the details of the national competent authorities in order to be in a position to proceed with the process.

(2) Update on the progress and discussion

An update on the general architecture of the system was presented by the DG SANTE IT representative. Following this a short presentation on the process for submitter ID registration was given, including a preview of the registration form and the information that will be required.

The main discussion points can be summarised as follows:

- DG SANTE asked participants regarding their connectivity to TestaNG and invited them to communicate any problems they may be experiencing. Some participants informed that they are still working on establishing connectivity but that progress is being made.
- DG SANTE reported from the connectivity pilot testing (for system-to-system/e-Delivery submissions) for industry and explained that to date 9 companies had registered, with successful connectivity already established in some cases. Registration will remain open for some more weeks to allow others to test their connectivity. Regarding end-to-end pilot testing (i.e. with test data), it was explained that registration will open next Monday 4 April. One participant asked if Member States will receive the test data submitted by industry. DG SANTE said it will look into this.
- DG SANTE underlined that documents uploaded on CircaBC at the beginning of the month remain valid for now, and that any further changes/new documents will be added as soon as possible once ready.
- It was clarified that MS have to indicate a national administrator for each section of the repository (e-cigarettes and tobacco products). The Commission will then provide access rights to the repository to this/these administrator(-s). Following this, the administrators can authorise subsequent users to view the relevant data, but the

responsibility remains with the national administrator. One participant asked if the administrator and the user can be the same person; DG SANTE informed that this is possible. It was clarified that specific IT expertise is not a requirement for the administrators and that authorisation of subsequent users is expected to be straightforward from a technical point of view.

- It was explained that registration for submitter IDs will likely open from mid-April. Companies will fill in a registration form to be placed on the EU-CEG webpage, and submit it to the email address indicated. Some time will be needed on the side of the Commission to process applications but it will endeavour to do this as efficiently as possible. DG SANTE reminded that Member States should endeavour to ensure that all stakeholders are aware of their obligations in this respect. It said the dedicated EU-CEG webpage can be useful for this purpose.[1]
- Some participants inquired about the possibility of receiving training on the reporting tool; DG SANTE said that it is looking into the possibility of having a Webinar on this and asked participants to communicate specific needs.
  A participant raised the issue of change of ownership, and asked whether a product acquired by another company would need to be re-notified using a new submitter ID. SANTE said it is likely that a new owner would need to make a new submission, but promised to come back with more details.

Conclusions

SANTE thanked participants. It said that, as requested, it will consider the possibility to organise a Webinar on the reporting tools and that participants will receive further details on this shortly.

[1] http://ec.europa.eu/health/euceg/